

Chapter 2.1.14 – Avian Influenza

The United States submitted a general comment on the expert panel and the review paper, two general comments on articles 2.1.14.1 and 2.1.14.12, and 5 specific comments on articles 2.1.14.1, .2, .13, .15, .17, and .18. Only two of the seven comments on the articles received a response, and those responses were either partial or unclear. We endorse those comments again; they remain valid and should be addressed. They are again included in this document for your convenience and to re-emphasize their importance. Additional observations and recommendations to our original comments are shown in ***bold and italics***.

We also offer the following **new specific comments on Articles 2.1.14.4 and 2.1.14.9** from the July 2003 Code Commission Report:

Article 2.1.14.4

Current text as proposed in the July 2003 Report :

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of live birds other than poultry:

the presentation of an *international veterinary certificate* attesting that the birds:

- 1) showed no clinical sign of AI on the day of shipment;
- 2) were kept in isolation ~~a quarantine station~~ since they were hatched or for the 28 days prior to shipment and showed no clinical sign of AI during the isolation ~~quarantine~~ period;
- 3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from AI.

Suggested Text:

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of live birds other than poultry:

the presentation of an *international veterinary certificate* attesting that the birds:

- 1) showed no clinical sign of AI on the day of shipment;
- 2) were kept in isolation ~~a quarantine station~~ since they were hatched or for the 28 days prior to shipment and showed no clinical sign of AI during the isolation ~~quarantine~~ period;
- 3) were subjected to a diagnostic test for antigen within 7 to 14 ~~to 14~~ days prior to shipment to demonstrate freedom from AI.

Rationale:

Article 2.1.14.4 covers birds other than poultry, which are not raised in captivity and which are not subject to the definition of AI. We believe that 14 days is too long a period to allow for testing in these types of animals. Allowing an antibody test instead of a specified test for antigen (virus isolation or molecular methods) in effect adds the period for seroconversion to the window during which infection could occur and not be detected prior to a shipment. It is interesting to note that, in Article 2.1.14.12, dealing with importation of fresh meat from a country not considered free of AI, a 7-day window of time and a virus detection test are specified. Since birds other than poultry would be of unknown AI status, it should be presumed that they could be infected, and requirements should be at least as stringent as for products from potentially exposed but presumably free birds.

Article 2.1.14.9**Current text as proposed in the July 2003 Report :**

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of semen of birds other than poultry.

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation ~~quarantine~~ for the 28 days prior to semen collection;
- 2) showed no clinical sign of AI during the isolation ~~quarantine~~ period;
- 3) were tested between 7 and 14 days prior to semen collection and shown to be free of AI.

Suggested Text:

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of semen of birds other than poultry.

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation ~~quarantine~~ for the 28 days prior to semen collection;
- 2) showed no clinical sign of AI during the isolation ~~quarantine~~ period;
- 3) were tested for antigen within ~~between 7 and 14 days~~ prior to semen collection and shown to be free of AI.

Rationale:

The rationale here is the same as for Article 2.1.14.4. In addition, semen, being frozen with cryo-preserved, could be easily contaminated and would preserve the live virus quite well.

Unanswered Comments from the United States as submitted following the December 2002 Code Commission Report – these are again being submitted with additional observations and comments shown in ***bold and italics***.

Chapter 2.1.14 – Avian Influenza

A specific comment is provided to the expert panel paper as follows:

Under the heading of “Molecular basis of virulence”, the next to the last sentence reads as follows:

‘For example, all H7 subtype viruses of low virulence have had the amino acid motif at the HA0 cleavage site of either -PEIPKGR*GLF- or -PENPKGR*GLF-...’

This statement can be easily misinterpreted since the two cleavage site sequences are not the only sequences of LP from H7 AI viruses. Other sequences have been reported and should be considered. For example, in the United States, 5 different cleavage site sequences have been seen for H7 LPAI viruses recovered from Live Poultry Markets. A rewording of the expert statement would be necessary to prevent any misunderstanding.

Suggested wording: ‘For example, ~~all~~ H7 subtype viruses of low virulence have **commonly** had the amino acid motif at the HA0 cleavage site of either -PEIPKGR*GLF- or -PENPKGR*GLF-...’

Article 2.1.14.1

General Comment:

The incubation period of 28 days is excessively long. The OIE Technical Disease Card on Highly Pathogenic Avian Influenza mentions an incubation period of only 3-5 days. We favor 28 days as the length for maintaining restrictions; however, this should be called “recommended quarantine period” and not incubation period. This comment applies to most chapters in the Code. ***This comment was not addressed in the second draft – July 2003 Report.***

Current OIE proposed text:

For the purposes of this *Code*, avian influenza (AI) is defined as ‘an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2 or by an influenza A virus of H5 or H7 subtype’.

Suggested text:

For the purposes of this *Code*, avian influenza (AI) is defined as ‘an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2, **or 75% or greater mortality in intravenous pathogenicity test with 4-8-week-old chickens,** or by an influenza A virus of H5 or H7 subtype’

Rationale

The definition with use of IVPI test results is specific for the EU legislation and not for OIE manual. The definition should be changed to accommodate equivalent alternative test methods and results. *This comment was not addressed in the second draft – July 2003 Report.*

Article 2.1.14.2.

Current OIE proposed text:

AI free country or compartment

A country or compartment may be considered free from AI when it has been shown that AI infection has not been present for the past 12 months. If infected poultry are slaughtered, this period shall be 6 months after the slaughter of the last infected poultry.

The AI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. Freedom of infection in a country or zone can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of AI infected enterprises of 1%. Freedom of infection in an enterprise can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of AI infection of 10%. Each establishment should be sampled to provide a 95% level of confidence of detecting a prevalence of AI of 20%. For commercial ducks the surveillance programme should be based on virus isolation or detection.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of AI infection of 20%. In the case of a enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of AI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use of identifiable sentinel birds.

Suggested text:

AI free country or compartment

A country or compartment may be considered free from AI when it has been shown that AI infection has not been present for the past 12 months. If infected poultry are slaughtered, this period shall be ~~6~~ 3 months after the slaughter of the last infected poultry.

The AI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. Freedom of infection in a country or zone can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of AI infected enterprises of 1%. Freedom of infection in an enterprise can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of

confidence of detecting a prevalence of AI infection of 10%. Each establishment should be sampled to provide a 95% level of confidence of detecting a prevalence of AI of 20%. For commercial ducks the surveillance programme should be based on virus isolation or detection. **Ongoing surveillance requirements can be satisfied by sampling the required number of establishments and enterprises at least quarterly.**

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of AI infection of 20%. In the case of an enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of AI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds, **or alternatively, use of applicable serological tests in identifiable sentinel birds will identify field infection in vaccinated flocks.** [Additional security should be provided by the use of identifiable sentinel birds.]

Rationale:

First suggested change: The length of the period for *regaining* AI free status if birds are slaughtered could be reduced from six to three months. We do not see the rationale for having different time periods for different currently listed List A diseases (FMD, CSF, AI) that are equally contagious. ***This comment was not addressed in the second draft – July 2003 Report.***

Second change: Statisticians indicate that sampling to achieve the desired levels of detection and confidence requires the sampling of 22 birds per enterprise, 46 enterprises per establishment, and 475 establishments per country or zone. Nowhere is there any reference to the frequency of testing. The frequency becomes critical in determining the total number of tests that must be performed in a given period of time, and thus the burden placed on laboratory systems. For example, in the U.S. broiler industry, there are far fewer than 475 enterprises (vertically integrated production complexes). We estimate that there are less than 200 such units, so essentially all will have to be sampled. In each enterprise, 22 birds from 46 establishments (farms) must be sampled per unit of time, for a total of 1,012 samples per enterprise per unit of time. In a concentrated area (such as north Georgia) with 10 to 15 enterprises served by one state laboratory, the total is 10,120 to 15,180 samples per unit of time. Sampling on a weekly or even monthly basis would overwhelm most laboratory systems in most areas of the world. On the other hand, sampling on a yearly basis would amount to less than one establishment per enterprise per week (46 establishments sampled per 52-week period), and is clearly inadequate. Performing the sampling on a quarterly basis appears to be an adequate but achievable number. **Note: *This paragraph was omitted from the second edition, but it is our understanding that it remains in the text. This comment was not addressed in the second draft – July 2003 Report.***

Third change: Differential tests are not always available or necessary to certify vaccinated birds as free of influenza infection. Sentinel bird studies in Italy and the United States have shown their value for detecting infections in vaccinated flocks. ***This comment was addressed in part. The second draft includes the following wording:***

“If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. ~~Additional security should be provided by~~ The use of relevant serological tests in identifiable sentinel birds will help to identify field infections in vaccinated flocks.”

While this wording is similar to what the United States suggested, it does not make clear that the use of sentinels is an alternative to tests that distinguish vaccinated from infected birds. We again recommend that the wording we suggested in our initial comments be used.

Other comments related to this article:

On the concept of compartmentalization: The chapter introduces the concept of compartmentalization as a tool to demonstrate freedom from disease, recognizing that different production systems and wild bird populations may have a different status concerning avian influenza. This approach is applicable to differentiate the disease status of broad populations under different management systems. However, defining compartments at the enterprise level, although scientifically valid, would be very complex to manage. This approach implies that a vertically integrated poultry company could be considered as one enterprise. According to the proposed definition, an enterprise is one or more establishments (i.e. farms) with an integrated system of animal management forming an autonomous epidemiological entity. Under this definition, the distance between farms in a defined geographical area is not considered relevant. If a compartment is defined as an enterprise, in the event of an outbreak, that compartment would be shut off. This could involve several farms potentially scattered over a broad geographical area, even in different states within a country. On the other hand, a poultry farm in the immediate vicinity of an infected farm but belonging to another enterprise would not be suspended from international trade. Compartments would need to be defined in very precise terms including the number, type ***and location of farms***, sharing of equipment and personnel and many other relevant factors.

In summary, we support applying the concept of compartmentalization to demonstrate the disease status of commercial poultry farms in countries or zones in which wild birds and backyard poultry farms may be infected. The use of compartmentalization as a tool to manage a disease incursion may not be practical at this time, or may need to be more clearly defined. Therefore, we recommend that the Code Commission develop a set of guidelines to provide a common benchmark to help apply the concept of compartmentalization.

Additional observations on the concept of compartmentalization: We agree that compartmentalization based on both production systems and geography may be more

appropriate. We are further proposing the following definition to distinguish commercial poultry from backyard poultry, game birds, etc. under US conditions:

“Commercial poultry are domesticated poultry grown on farms either owned by or under written contract with a processor or a feed company, and whose eggs, progeny, or the birds themselves are processed in federal or state government inspected plants for eventual sale to the public as food eligible for interstate commerce; and poultry for breeding these categories of birds”.

Commercial products should not be penalized when Avian Influenza occurs in wild or backyard birds, and when the exporting country can demonstrate a clear and documented epidemiological separation between the commercial and backyard segments (compartments).

Article 2.1.14.12

General Comment:

The Animal Health Code Commission should give consideration to having different requirements for subtypes that are highly pathogenic and those shown to be of low pathogenicity. While we support the international reporting of all H5 and H7 virus detections, we would suggest differential trade requirements for meat and products originating from countries, zones or compartments depending on the virulence of the strain. The lumping of all H5 and H7 as ‘eradicable viruses by OIE’ raises concern about interpretation of the information by individual nations. HPAI viruses cause severe diseases with high death losses and significant economic losses. Their elimination should be by stamping-out programs. The LPAI viruses of H5 and H7 subtype do not cause systemic disease like HPAI viruses, but economically produce lower losses as with non-H5 & H7 LPAI. However, H5 and H7 LPAI viruses should not be allowed to become endemic or the potential for emergence of HPAI will increase. H5 and H7 LPAI viruses should have control and eradication programs, however, lumping them with HPAI viruses suggests that stamping-out programs are the only acceptable means for controlling such viruses.

The threat of economic losses and transmission by LPAI H5 and H7 viruses are less than those of HPAI viruses. Therefore, control programs should recognize this fact and allow alternative approaches to a stamping-out program. Thus a vaccination program plus controlled marketing will work towards elimination and prevent emergence of HPAI viruses. Furthermore, studies have not shown meat to be a means of dissemination of LPAI viruses as could occur with HPAI viruses. Statements in the section of meat and meat products will adversely affect trade by lumping all H5 and H7 together. There needs to be some distinction in control/eradication plans and their impact on imports between H5 and H7 LPAI and HPAI viruses in the OIE code chapter.

Further comment/observation: Although Article 2.1.14.12 bis (from the July 2003 Report) partially addresses these concerns in regard to importation of fresh meat from areas with low pathogenic H5 or H7 AI, the additional concerns expressed in our comments are not adequately addressed in the second draft.

Articles 2.1.14.13, 15, 17 and 18

It would be useful to provide guidelines on appropriate procedures to destroy the AI virus. The current OIE Technical Disease Card on Highly Pathogenic Avian Influenza does provide guidance but the International Committee has not approved them for inclusion in the Code. We suggest the development of an appendix to be included under section 3.6 of the Code.

Excerpt from the Technical Disease Card:

Resistance to physical and chemical action

Temperature: Inactivation by 56°C/3 hours; 60°C/30 min

pH: Inactivated by acid pH

Chemicals: Inactivated by oxidizing agents, sodium dodecyl sulphate, lipid solvents, β -propiolactone

Disinfectants: Inactivated by formalin and iodine compounds

Survival: Remains viable for long periods in tissues, feces and also in water

This comment on multiple articles was not addressed in the second draft.

Further observation/comment: We also recommend that the Code Commission establish a list of processed poultry products which can be safely traded without restriction independent of AI status.

The United States also would like to make one additional comment to the text of the December 2002 Code Commission Report. The comment pertains to Article 2.1.14.5.

Current OIE proposed text (from December 2002 Report):

Article 2.1.14.5

When importing from an AI free country or compartment, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) showed no clinical sign of AI on the day of shipment;
- 2) were kept in an AI free country or compartment since they were hatched;

Note: If the day-old poultry or the parents of the poultry were vaccinated against AI, the details of the vaccine and the date of vaccination should be provided.

Suggested text:

When importing from an AI free country or compartment, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) ~~showed no clinical sign of AI on the day of shipment;~~ the flocks producing the day-old birds showed no clinical signs of AI within 30 days prior to the setting of the eggs;
- 2) were kept in an AI free country or compartment since they were hatched;

Note: If the day-old poultry or the parents of the poultry were vaccinated against AI, the details of the vaccine and the date of vaccination should be provided.

Rationale: The health of the parent flock producing the offspring is a better barometer of the health of the day-old chicks than examining the chicks on the shipment date. In addition, the logistics of examining a parent flock by the attending veterinarian is more feasible and meaningful.